Summary of Safety and Effectiveness
Line Extension to the Apex® Fixation Pins

Submission Information

Name and Address of the Sponsor of the 510(k) Submission	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	April 12, 2001

Device Identification

Proprietary Name:	Apex® Fixation Pins
Common Name:	Fixation Pins
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR §888.3040

Predicate Device Identification

The Apex® Fixation Pins were determined substantially equivalent via 510(k) K861766. There are 3,4 and 5 mm diameter pins cleared in a variety of overall lengths and thread lengths. A change in sterility was determined substantially equivalent via 510(k) K001886 which allowed the pins to also be incorporated into sterile kits.

Device Description

The line extension to the system adds the following pins: 6 mm diameter Apex ® Self-Drilling Half Pins, 6 mm diameter Apex ® Blunt Half Pins, 5/6 mm diameter Apex ® Transfixing Pins and 5 mm diameter Apex ® Cancellous Half Pins. The modifications involve changing the shaft diameter and major and minor thread diameters. The material, thread geometry, cutting flutes and tip remains the same.

Intended Use:

The intended use of the subject device, as described in the labeling, has not changed as a result of the modification. These devices are intended to be inserted into the bone nearest a fracture site and connected externally to a rigid external supporting frame for immobilization of unstable fractures. The pins are designed to ease bone penetration and minimize the risk of friction thermal necrosis, thereby facilitating secure bone purchase and stable fixation of the fracture.

Statement of Technological Comparison:

Engineering analysis demonstrates comparable mechanical properties of the subject to the predicate pins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2001

Ms. Elizabeth S. Staub
Vice President, Regulatory Affairs
Stryker Howmedica Osteonics
59 Route 17
Allendale, New Jersey 07401

Re: K011136
Trade/Device Name: Apex® Fixation Pins
Regulation Number: 888.3040
Regulatory Class: II
Product Code: JDW
Dated: April 12, 2001
Received: April 13, 2001

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K011136

Device Name: Apex® Fixation Pins

Indications For Use:

The Apex® Fixation Pins are intended to be used in conjunction with a rigid external supporting frame for immobilization of open and/or unstable fractures and where the soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting and other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

(Per 21 CFR 801.109) (Optional Format 1-2-96)

D Mitchell MD for CMW

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K011136